5. 510(k) Summary

JAN 10 2012

Device Trade Name: DSS™ Stabilization System - Rigid

Manufacturer: Paradigm Spine, LLC
505 Park Avenue, 14th Floor
New York, NY 10022

Contact: Ms Michelle McDonough
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Phone: (202) 552-5800
Fax: (202) 552-5798

Date Prepared: January 9, 2012

Classification: 21 CFR §888.3070, Pedicle screw spinal system

Class: III

Product Code: MNH, MNI, NKB

Indications For Use:

DSS™ Stabilization System - Rigid

The DSS™ Stabilization System – Rigid is intended as a single-level system for noncervical pedicle fixation from the T4 to S1 vertebrae in skeletally mature patients to help provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion. The DSS™ Stabilization System – Rigid is intended to be used with autograft and/or allograft.

DSS™ Stabilization System - Slotted

The DSS™ Stabilization System - Slotted is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, kyphosis, and failed previous fusion (pseudarthrosis).

In addition, the DSS™ Stabilization System - Slotted is indicated for use in patients:

- Who are receiving fusions with autogenous graft only;

- Who are having the device fixed or attached to the lumbar or sacral spine;
- Who are having the device removed after the development of a solid fusion mass.

Note: The Rigid Coupler and Slotted Coupler are not intended to be used together.

Device Description:
The DSS™ Stabilization System is comprised of a variety of pedicle screws sizes, and couplers that act as longitudinal spacers that are uniquely fitted for each individual case. The pedicle screws and couplers are manufactured from medical grade titanium alloy (Ti6Al4V).

The purpose of this Special 510(k) is to add a straight rod, straight rod with pan, and polyaxial screw to the DSS Stabilization System - Rigid. The modifications are intended to allow the operating surgeon to better accommodate patient anatomies with more construct options. The modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device.

Predicate Device(s):
DSS™ Stabilization System - Rigid was shown to be substantially equivalent to previously cleared devices (K022949, K024096, K042962, K072022, K080241, K090099, K090408, K090408, and K101083) and has the same indications for use, design, function, and materials used.

Substantial Equivalence:
Performance testing per ASTM F1717 (static compression bending, static torsion, dynamic compression bending) indicates the DSS™ Stabilization System - Rigid has equivalent performance to predicate devices.

Conclusion:
The DSS™ Stabilization System - Rigid is substantially equivalent to previously cleared devices with respect to its indications for use, design, function, materials and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Paradigm Spine, LLC
% Musculoskeletal Clinical Regulatory Advisers, LLC
Ms. Michelle McDonough
1331 H Street NW, 12th Floor
Washington, District of Columbia 20005

JAN 10 2012

Re: K113625
Trade/Device Name: DSS Stabilization System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: December 7, 2011
Received: December 12, 2011

Dear Ms. McDonough:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

"The safety and effectiveness of this device has not been established for the intended use of spinal stabilization without fusion. This device is only intended to be used when fusion with bone graft is being performed at all instrumented levels."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christy Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K113625

Device Name: DSS™ Stabilization System

DSS™ Stabilization System - Rigid
The DSS™ Stabilization System – Rigid is intended as a single-level system for noncervical pedicle fixation from the T4 to S1 vertebrae in skeletally mature patients to help provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion. The DSS™ Stabilization System – Rigid is intended to be used with autograft and/or allograft.

DSS™ Stabilization System - Slotted
The DSS™ Stabilization System – Slotted is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, kyphosis, and failed previous fusion (pseudarthrosis).

In addition, the DSS™ Stabilization System - Slotted is indicated for use in patients:

- Who are receiving fusions with autogenous graft only;
- Who are having the device fixed or attached to the lumbar or sacral spine;
- Who are having the device removed after the development of a solid fusion mass.

Note: The Rigid Coupler and Slotted Coupler are not intended to be used together.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113625